

ALTERNATIVE TO PTO/SB/08a/b (06-03)

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/646,070
				Filing Date	August 22, 2003
				First Named Inventor	Michael W. GRAHAM
				Art Unit	1696 1625
				Examiner Name	D. Sullivan Whitman
Sheet	1	of	1	Attorney Docket Number	546322000303

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>4</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
BW	1.	WO-99/09045	02-25-1999	Somagenics, Inc.		

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	2.	European Search Report mailed June 3, 2005, for European patent application no. 04015041, filed March 19, 1999, 4 pages	
BW	3.	BASS, Brenda L. (May 24, 2001) "RNA Interference: The Short Answer," Nature, 411:428-429	
BW	4.	HARBORTH, Jens et al. (2001) "Identification of Essential Genes in Cultured Mammalian Cells Using Small Interfering RNAs," Journal of Cell Science, 114:4557-4565	
BW	5.	MANCHE, Lisa et al. (Nov. 1992) "Interactions Between Double-Stranded RNA Regulators and the Protein Kinase DAI," Molecular and Cellular Biology, 12(11):5238-5248	
BW	6.	PADDISON, Patrick J. et al. (July 2002) "RNA Interference: The New Somatic Cell Genetics?" Cancer Cell, 2:17-23	

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Examiner Signature	/Brian Whiteman/	Date Considered	06/12/2006
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ALTERNATIVE TO PTO/58/06a/b (06-03)

Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/846,070
		Filing Date	August 22, 2003
		First Named Inventor	Michael W. GRAHAM
		Art Unit	4636 162
		Examiner Name	D. Sullivan Whiteman
Sheet	1	of	1
		Attorney Docket Number	546322000303

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
BW	AA	US 5,578,716	11-26-1996	Szyf et al.	
BW	AB	US 5,998,383	12-07-1999	Wright et al.	

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Examiner/ Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
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BW	BA	WO 95/15378	08-08-1995			

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BW	CA	Agrawal et al. (2000) "Antisense therapeutics: Is it as simple as complementary base recognition?" Molecular Medicine Today 6: 72-81.			
	CB	Cameron et al. (1994) "Multiple Domains in a Ribozyme Construct Confer Increased Suppressible Activity in Monkey Cells" Antisense Research and Development 4: 87-94.			
	CC	Harborth et al. (2003) "Sequence, Chemical, and Structural Variation of Small Interfering RNAs and Short Hairpin RNAs and the Effect on Mammalian Gene Silencing" Antisense and Nucleic Acid Drug Development 13: 83-105.			
	CD	Holen et al. (2002) "Positional effects of short Interfering RNAs targeting the human coagulation trigger Tissue Factor" Nucleic Acids Research 30 (8): 1757-1766.			
	CE	Jen et al. (2000) "Suppression of Gene Expression by Targeted Disruption of Messenger RNA: Available Options and Current Strategies" Stem Cells 18: 307-319.			
	CF	McManus et al. (2002) "Gene Silencing using micro-RNA designed hairpins" RNA 8: 842-850.			
	CG	McManus et al. (2002) "Small Interfering RNA-Mediated Gene Silencing in T Lymphocytes" Journal of Immunology 169: 5754-5760.			
	CH	Opalinska et al. (2002) "Nucleic-Acid Therapeutics: Basic Principles and Recent Applications" Nature Reviews 1: 503-514.			
BW	CI	Randall et al. (2003) "Clearance of replicating hepatitis C virus replicon RNAs in cell culture by small interfering RNAs" PNAS 100 (1): 235-240.			

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Examiner Signature	/Brian Whiteman/	Date Considered	06/12/2006
sf-1876556			



ALTERNATIVE TO PTO/SB/08a/b (06-03)

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/646,070
				Filing Date	August 22, 2003
				First Named Inventor	Michael W. GRAHAM
				Art Unit	4636 1635
Examiner Name	D. Sullivan Whitcomb				
Sheet	1	of	2	Attorney Docket Number	546322000303

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Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
BW	AA	US 4,766,072	08-23-1988	Jendrisak et al.	
	AB	US 5,190,931	03-02-1993	Inouye	
	AC	US 5,208,149	05-04-1993	Inouye	
	AD	US 5,272,065	12-21-1993	Inouye et al.	
	AE	US 2003/0056235 A1 with amendments	03-20-2003	Fire et al.	
	AF	US 2004/0237145 A1	11-25-2004	Graham et al.	
	AG	US 2003/0159161 A1	08-21-2003	Graham et al.	
	AH	US 2004/0180439 A1	09-16-2004	Graham et al.	
	AI	US 2004/0266005 A1	12-30-2004	Graham et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
BW	BA	WO 97/44450	11-27-1997		
BW	BB	WO 03/022052	03-20-2003		
BW	BC	WO 03/056012	07-10-2003		

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
BW	CA	COHLI ET AL. (1994) "Inhibition of HIV-1 multiplication in a human CD4+ lymphocytic cell line expressing antisense and sense RNA molecules containing HIV-1 packaging signal and Rev response element(s)" Antisense Research and Development 4: 19-26.	
	CB	FIRE ET AL. (1991) "Production of Antisense RNA Leads to Effective and Specific Inhibition of Gene Expression in C. Elegans Muscle" Development, 113(2): 503-514.	
BW	CC	FRASER ET AL. (1996) "Effects of c-myc first exons and 5' synthetic hairpins on RNA translation in oocytes and early embryos of Xenopus laevis" Oncogene 12(6):1223-30.	
	CD	<del>Hungarian Patent Office Search Report mailed July 13, 2004, for Hungary patent application no. P0101225, 1 page.</del>	
BW	CE	KIBLER ET AL. (1997) "Double Stranded RNA is a Trigger for Apoptosis in Vaccinia Virus Infected Cells" Journal of Virology, 71(3): 1992-2003.	
	CF	KNOESTER ET AL. (1997), "Modulation of Stress-Inducible Ethylene Biosynthesis by Sense and Antisense Gene Expression in Tobacco", Plant Science 126(2): 173-183.	

Examiner Signature	Date Considered
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sf-1856851

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete If Known</b>	
				Application Number	10/646,070
				Filing Date	August 22, 2003
				First Named Inventor	Michael W. GRAHAM
				Art Unit	1636
				Examiner Name	D. Sullivan
Sheet	2	of	2	Attorney Docket Number	546322000303

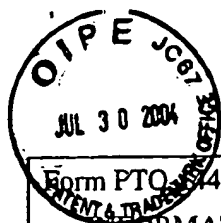
BW	CG	KOZAK (1989) "Circumstances and mechanisms of inhibition of translation by secondary structure in eucaryotic mRNAs" Mol. Cell. Biol. 9:5134-5142.	
	CH	LIEBHABER ET AL. (1992) "Translation inhibition by an mRNA coding region secondary structure is determined by its proximity to the AUG initiation codon" J. Mol. Biol. 226:609-621.	
	CI	LINGELBACH ET AL. (1988) "An extended RNA/RNA duplex structure within the coding region of mRNA does not block translational elongation" Nuc. Acids Res. 16 3405-3414.	
	CJ	LOOMIS ET AL. (1991) "Antisense RNA inhibition of expression of a pair of tandemly repeated genes results in a delay in cell-cell adhesion in Dictyostelium" Antisense Res. Dev.1:255-260.	
	CK	MIKOSHIBA ET AL. (1991) "Molecular biology of myelin basic protein: gene rearrangement and expression of anti-sense RNA in myelin-deficient mutants" Comp. Biochem. Physiol. 98:51-61.	
	CL	OKANO ET AL. (1991) "Myelin basic protein gene and the function of antisense RNA in its repression in myelin-deficient mutant mouse" J. Neurochem. 56:560-567.	
	CM	PELLETIER ET AL. (1985) "Insertion mutagenesis to increase secondary structure within the 5' noncoding region of a eukaryotic mRNA reduces translational efficiency" Cell, 40:515-526.	
	CN	PICCIN ET AL. (2001) "Efficient and Heritable Functional Knock-out of an Adult Phenotype in Drosophila using a GAL4-Driven Hairpin RNA Incorporating a Heterologous Spacer" Nucleic Acids Research, 29(12) E55:1-5.	
	CO	SVOBODA, P. ET AL. (2001) "RNAi in Mouse Oocytes and Preimplantation Embryos: Effectiveness of Hairpin dsRNA" Biochem Biophys Res Commun., 287(5): 1099-1104.	
	CP	WATSON (1988) "A new revision of the sequence of plasmid pBR322" Gene 70:399-403.	
BW	CQ	WEAVER ET AL. (1981) "Introduction by molecular cloning of artifactual inverted sequences at the 5' terminus of the sense strand of bovine parathyroid hormone cDNA" PNAS 78: 4073-4077.	

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Examiner Signature	/Brian Whiteman/	Date Considered	06/12/2006
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sf-1856851



Form PTO/SB/08-149

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 546322000303

Application Number 10/646,070

Applicants

Michael Wayne GRAHAM et al.

Filing Date August 22, 2003

Group Art Unit ~~1632~~ 1635

Mailing Date July 27, 2004

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
BW	1.	8/25/1998	* 5,798,265	Springer et al.			
	2.	7/4/2002	* 2002/0086356 A1	Tuschl et al.			
	3.	8/22/2002	* 2002/0114784 A1	Li et al.			
	4.	2/6/2003	* 2003/0027783 A1	Zernicka-Goetz			
	5.	4/29/1997	*5,624,803	Noonberg et al.			
	6.	4/25/2000	*6,054,299	Conrad			
	7.	7/23/2002	*6,423,885	Waterhouse et al.			
	8.	6/3/2003	*6,573,099	Graham			
	9.	9/29/1998	*5,814,500	Dietz			
	10.	1/14/2003	*6,506,559	Fire et al.			
	11.	2/1/94	*5,283,184	Jorgensen et al.			
	12.	7/27/93	*5,231,020	Jorgensen et al.			
	13.	7/23/91	*5,034,323	Jorgensen et al.			
	14.	12/10/96	*5,583,021	Dougherty, et al.			
	15.	11/11/97	*5,686,649	Chua, et al.			
	16.	2/3/98	*5,714,323	Oshima, et al.			
	17.	1/23/03	*2003/0018993 A1	Gutterson et al.			
	18.	2/20/03	*2003/0036197 A1	Glassman et al.			
	19.	3/20/03	*2003/0056235 A1	Fire et al.			
	20.	4/17/03	*2003/0074684 A1	Graham et al.			
BW	21.	09/04/03	2003/0165894 A1	Waterhouse et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
BW	22.	6/9/99	* EP 0 921 195 A1	EP			
BW	23.	8/7/02	* EP 1 229 134 A1	EP			

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<b>Form PTO-1449</b> <b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i>					Docket Number <b>546322000303</b>		Application Number <b>10/646,070</b>	
					Applicants <b>Michael Wayne GRAHAM et al.</b>			
					Filing Date <b>August 22, 2003</b>		Group Art Unit <b>1632</b>	
					Mailing Date <b>July 27, 2004</b>			

BW	24.	1/13/00	* WO 00/01846	WIPO				
	25.	10/26/00	* WO 00/63364	WIPO				
	26.	4/26/01	* WO 01/29058	WIPO				
	27.	5/25/01	* WO 01/36646	WIPO				
	28.	1/18/01	* WO 01/04313	WIPO				
	29.	7/5/01	* WO 01/48183	WIPO				
	30.	11/22/01	* WO 01/88114	WIPO				
	31.	6/6/02	* WO 02/44321	WIPO				
	32.	1/23/03	* WO 03/006477	WIPO				
	33.	5/7/98	*WO 98/18811	WIPO				
	34.	10/21/99	*WO 99/53050	WIPO				
	35.	9/27/01	*WO 01/70949	WIPO				
	26.	4/3/03	*WO 03/27298	WIPO				
	37.	7/1/99	*WO 99/32619	WIPO				
	38.	4/20/95	*WO 95/10607	WIPO				
	39.	10/8/98	*WO 98/44138	WIPO				
	40.	3/21/96	*WO 96/08558	WIPO				
	41.	9/15/93	*EP 0560156A2	EPO				
	42.	5/27/99	*WO 99/25853	WIPO				
	43.	10/21/97	*EP 0242016	EPO				
	44.	8/20/98	*WO 98/36083	WIPO				
	45.	4/1/99	*WO 99/15682	WIPO				
	46.	1/23/97	*WO 97/01952	WIPO				
	47.	11/25/93	*WO 93/23551	WIPO				
	48.	8/4/94	*WO 94/17194	WIPO				
	49.	9/2/93	*WO 93/17098	WIPO				
	50.	11/26/98	*WO 98/53083	WIPO				
	51.	10/18/90	*WO 90/11682	WIPO				
	52.	8/27/98	*WO 98/37213	WIPO				
	53.	9/30/99	WO 99/49029	WIPO				
BW	54.	02/01/01	AU 729454	Australia				

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sf- 1741781PTO/SB/ 08 (2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

<b>Form PTO-1449</b> <b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i>					Docket Number 546322000303		Application Number 10/646,070	
					Applicants			
					Michael Wayne GRAHAM et al.			
					Filing Date August 22, 2003		Group Art Unit 1632	
					Mailing Date July 27, 2004			

BW	55.	11/12/92	WO 92/19732	WIPO				
	56.	01/20/94	WO 94/01550	WIPO				
	57.	12/02/99	WO 99/61631	WIPO				
	58.	08/03/00	WO 00/44895	WIPO				
	59.	08/03/00	WO 00/44914	WIPO				
	60.	06/14/95	EP 0465572	EPO				
BW	61.	08/31/95	WO 95/23225	WIPO				

**OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)**

Examiner Initials	Ref. No.	Title
BW	62.	* Billy, E. et al. (2001) "Specific interference with gene expression induced by long, double-stranded RNA in mouse embryonal teratocarcinoma cell lines" Proceedings of the National Academy of Sciences of the United States of America 98(25): 14428-33.
	63.	* Brummelkamp, R. et al. (2002) "A System for Stable Expression of Short Interfering RNAs in Mammalian Cells" Science Vol. 296: 550-553.
	64.	* Dykxhoorn, D. et al. (2003) "Killing the Messenger: Short RNAs that Silence Gene Expression." Nature Reviews Molecular Cell Biology Vol.4: 457-467.
	65.	* Elbashir, S.M. et al. (2001) "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells" Nature 411(6836): 494-8.
	66.	* Matzke, Marjori A. and A. J. M. Matzke (1995) "How and Why Do Plants Inactivate Homologous (Trans) genes" Plant Physiol. 107: 679-685.
	67.	* Svoboda, P. et al. (2000) "Selective reduction of dormant maternal mRNAs in mouse oocytes by RNA interference" Development 127(19): 4147-4156.
	68.	* Wang, et al. "A factor IX-deficient mouse model for hemophilia B gene therapy" PNAS 94: 11563-11566.
	69.	* Yang, S. et al. (2001) "Specific double-stranded RNA interference in undifferentiated mouse embryonic stem cells" Molecular and Cellular Biology 21(22): 7807-16.
	70.	* International Search Report mailed on May 10, 1999, for PCT patent application no. PCT/AU99/00195, filed on March 19, 1999, 3 pages.
	71.	* Birchler, James A. (2000) "Making noise about silence: repression of repeated genes in animals" Current Opinion in Genetics & Development 10: 211-216.
BW	72.	* Brummell, David A. et al. (2003) "Inverted repeat of a heterologous 3'-untranslated region for high-efficiency, high-throughput gene silencing" The Plant Journal 33: 793-800.

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sf- 1741781PTO/SB/08 (2-92)
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

<b>Form PTO-1449</b>  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>		Docket Number 546322000303	Application Number 10/646,070
		Applicants  Michael Wayne GRAHAM et al.	
		Filing Date August 22, 2003	Group Art Unit 1632
		Mailing Date July 27, 2004	

BW	73.	*Cogoni, Carlo and Giuseppe Macino (2000) "Post-transcriptional gene silencing across kingdoms" Current Opinion in Genetics & Development 10: 638-643.
	74.	*Marathe, Rajendra et al. (2000) "RNA viruses as inducers, suppressors and targets of post-transcriptional gene silencing" Plant Molecular Biology 43: 295-306.
	75.	*Matzke, Marjori and Antonius J.M. Matzke (2003) "RNAi Extends Its Reach" Science: 1060-1061.
	76.	*Oates, Andrew C. et al. (2000) "Too Much Interference: Injection of Double-Stranded RNA Has Nonspecific Effects in the Zebrafish Embryo" Developmental Biology 224: 20-28.
	77.	*Putlitz, Jasper zu and Jack R. Wands (1999) Specific Inhibition of Hepatitis B Virus Replication by Sense RNA " Antisense & Nucleic Acid Drug Development 9: 241-252.
	78.	*Schramke, Vera and Robin Allshire (2003) "Hairpin RNAs and Retrotransposon LTRs Effect RNAi and Chromatin-Based Gene Silencing" Science 301: 1069-1074.
	79.	*Tavernarakis, Nektarios et al. (2000) "Heritable and inducible genetics interference by double-stranded RNA encoded by transgenes" Nature Genetics 24: 180-183.
	80.	*Ui-Tei, Kumiko et al. (2000) "Sensitive assay of RNA interference in <i>Drosophila</i> and Chinese hamster cultured cells firefly luciferase gene as target" Federation of European Biochemical Societies Letters 479: 79-82.
	81.	*Wargelius, Anna et al. (1999) "Double-Stranded RNA Induces Specific Developmental Defects in Zebrafish Embryos" Biochemical and Biophysical Research Communications 263: 156-161.
	82.	*Fire, A., Xu, S.Q., Montgomery, M.K. Kostas, S.A. Driver, S.E. and Mello, C.C. (1998), "Potent and Specific Genetic Interference by Double-Standard RNA in <i>Caenorhabditis elegans</i> ". Nature, 391 (6669): 806-811.
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